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10/783,522	02/20/2004	Roy Lurie	MWS-109RCE	7481
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EXAMINER				
WHALEY, PABLO S				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/783,522

**Applicant(s)**

LURIE ET AL.

**Examiner**

PABLO WHALEY

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 37-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CIS) Paper No(s)/Mail Date 3/25/2009
- 4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This application contains claims 37-50 drawn to an invention nonelected with traverse in the reply filed on 07/31/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim 22 recites the phrase “means for”, wherein the “means for” language is modified by functional language directed to accessing a block diagram model, generating a result, gathering data, and comparing the generating result. However, the “means for” phrase properly invokes 35 USC 112 6<sup>th</sup> paragraph because the means for performing the specified functions without the recital of structure is sufficiently described in the specification.

#### ***Status of Claims***

Claims 1-50 are pending.

Claims 1-36 are rejected.

Claims 37-50 are withdrawn.

Claim 51 is cancelled.

#### ***Information Disclosure Statement***

The information disclosure statement filed 03/25/2009 has been considered in full. ***Inventorship***

Applicant’s petition to correct inventorship under 37 CFR 1.48(a) has been fully considered. In view of the papers filed 03/11/2009, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by removing Edward Whittington as an inventor. The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

***Application Data Sheet***

The ADS, filed 03/11/2009, is not compliant with 37 CFR 1.76(c)(2). It must be titled "Supplemental Application Data Sheet." Applicant is required to provide a corrected supplemental ADS.

***Objections***

The objection to claim 12 is withdrawn in view of applicant's amendment filed 01/07/2009.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-21 are directed to a method for modifying a model. A claimed process is statutory under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter), or (2) it transforms a particular article into a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008; In re Comiskey, Fed. Cir., No. 2006-1286).

Regarding the required tie to a particular machine or apparatus, the process required by claims 12-21 are not limited to a particular apparatus or machine. For example, the claimed subject matter does not recite any specific machine for comparing results or modifying a model. Although the claims recite a step for gathering data from an in situ device, insignificant data gathering or post-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. The applicants are cautioned against introduction of new matter in an amendment.

Regarding the transformation test, the claimed subject matter does not recite a physical transformation of matter. For example, the claimed subject matter is directed to data gathering and

manipulation [See *In re Grams*, 12 USPQ2d 1824 (Fed Cir. 1989)]. This rejection could be overcome by amendment of the claims to recite a step wherein an article is reduced to a different state or thing (e.g. physical assay), or a step wherein data representing a physical object or substance that is obtained by a specific physical process is sufficiently manipulated or changed (e.g., raw data into a particular visual depiction of a physical object on a display) [See *In re Abele*, 684, F.2d at 908-909, CCPA, 1982 ]. The applicants are cautioned against introduction of new matter in an amendment.

### ***Response to Arguments***

Applicant's arguments, filed 01/07/2009, that the claims are statutory in view *In re Bilski* which discards the concrete, tangible, and useful requirement have been fully considered and are persuasive.

Applicant's arguments, filed 01/07/2009, that the claimed subject matter is limited to a particular apparatus or machine have been fully considered but are not persuasive. In response, the method recited in claim 12-21 does not recite any specific machine for comparing results or modifying a model. Although the claims recite a step for gathering data from an in situ device, insignificant data gathering or post-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. This rejection is maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly

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owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 12-19, 21, 24, 28, and 31 are rejected under 35 U.S.C. 103(a) as being made obvious by Potts et al. (US Pat. No. 6,882,940; Filed Aug. 10, 2001), in view of Fox et al. (Published 22 May 2003; IDS filed 11/8/2004).

This new ground of rejection is necessitated by applicant's amendment, filed 01/07/2009.

Potts teaches a computer program for predicting a hypoglycemic event in a subject [Abstract]. Potts describes system components, input/output functions, and software (i.e. instructions) for executing programs [Col. 2, Col. 3, Col. 6, ¶4], and shows generating values using an algorithm and multi-level decision tree model [Col. 24, Section 2.8, and Col. 27]. Potts shows a system for gathering data directly from a transdermal sampling system at set time intervals [Col. 2], which shows gathering data directly from an in situ device on which an ongoing experiment is being conducted, as in claims 1, 12, 22, and 28. Potts teaches generating predicted glucose measurement values (i.e. expected results) [Col. 3, lines 40-60], as in claims 1, 12, 22, and 28. Potts teaches comparing skin conductance readings (i.e. in situ experimental data) with threshold values to determine hypoglycemic events (i.e. expected results) [Reference claims 1 and 25], and teaches correlating (i.e. comparing) blood glucose measurements with "out of sample" predictions made the model [Col. 18, lines 45-67], as in claims 1, 12, 22, and 28. Potts teaches steps for modifying the predictive model based on comparisons to gathered blood glucose values and parameters need to minimize model error [Col. 18, lines 45-60], which shows modifying a model based on comparison to correct the model, as in claims 1, 12, 22, and 28. The system allows for the storage of data to memory [Col. 16, lines 55-65]. Potts teaches an alert signal (i.e. event signal) generated

when glucose amount is outside of the predetermined range of values [Co. 7, lines 20-23], as in instant claims 15, 24, and 31. Potts teaches a prediction system (i.e. modeling environment) allowing for user-settable threshold levels [Col. 13, lines 20-25], which is a teaching for modifying the model based on optimization means (i.e. thresholding), as in claim 12. Potts teaches methods for extracting glucose from a subject glucose into reservoirs and techniques and/or devices for generating glucose data [Col. 3, lines 25-35], which shows gathering and analyzing in situ data, as in claims 12 and 22. Potts teaches the display, operative connection, and wireless transmission of data [Col. 18, lines 5-25], as in instant claims 13, 14, and 18. The Glucowatch prediction system (i.e. modeling environment) allows for user-settable threshold levels [Col. 13, lines 20-25] and comprising an LCD screen and user interface [Col. 16, lines 60-65], as in instant claims 16-17. A predictive Taylor-Series expansion model for adjusting glucose values to predict future values [Equation (7), Reference claim 7], which is a teaching for generating a refined model as in instant claim 19. The GlucoWatch biographer comprises a microprocessor (i.e. analyte monitoring device and display unit) for measuring and analyzing glucose levels from a subject via ionophoresis [Col. 7, lines 15-23], which is a teaching for in situ experimentation and a device as in instant claim 21.

Potts does not specifically teach executing a block diagram of a biological process, as in claims 1, 12, 22, and 28.

Fox teaches a method and program for modeling biological processes using block diagrams [Ref. claims 9, 11, Fig. 7, Fig. 8].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the method and program of Potts by representing predictive algorithms using block diagrams, as in claims 1, 12, 22, and 28, since Fox teaches a method and program for modeling biological processes using executable block diagrams [Ref. claim 9, 11, Fig. 7, Fig. 8]. The motivation would have

been to represent the logical flow of information pertaining to complex biological processes in a user friendly format.

### ***Response to Arguments***

Applicant's arguments, filed 01/07/2009, that Potts does not teach generating a result from a block diagram model have been fully considered and are persuasive. Therefore this rejection of Potts under 35 USC 102 is withdrawn. A new ground of rejection has been applied in view of applicant's amendments. Regarding applicant's additional arguments that Potts does not teach comparing the generated result to data obtained from an experimental device, and modifying the model of the biological process based on the comparison have been fully considered but are not persuasive. Potts teaches steps for modifying the predictive model based on comparisons blood glucose values obtained from an experimental device (i.e. Glucowatch) [Col. 6, Col. 18, lines 45-60], which shows modifying a model based on comparison to correct the model. Potts teaches comparing skin conductance readings (i.e. in situ experimental data) with threshold values to determine hypoglycemic events (i.e. expected results) [Reference claims 1 and 25], and teaches correlating (i.e. comparing) blood glucose measurements with "out of sample" predictions made the model [Col. 18, lines 45-67]. Potts teaches a prediction system (i.e. modeling environment) allowing for user-settable threshold levels [Col. 13, lines 20-25], which is a teaching for modifying the model based on optimization means.

Claims 1-30 and 32-36 are rejected under 35 U.S.C. 103(a) as being made obvious by Goryanin et al. (Bioinformatics, 1999, Vol. 15, No. 9, p.749-758), in view of Bubendorf et al. (Journal of Pathology, 2001, Vol. 195, p.72-79).

Goryanin teaches a method, system, and program (*DBsolve*) comprising models for the mathematical simulation and analysis of cellular metabolism and regulation. In particular, Goryanin teaches analysis models (i.e. simulation engines) model metabolic pathways, receive input, generate



output, and display results via the operably connected model designer [Fig. 1 and Fig. 3]. The model is presented using a block diagram that models biological processes [Fig. 2 and p.750, Col. 2]. Goryanin teaches an analysis environment in communication with said simulation engine and comparing model data to experimental data for optimization [Fig. 1] and [p.753, Col. 2, ¶ 2]. Goryanin teaches instructions for model refinement based on a comparison of the applied model parameters (i.e. expected results) with observed experimental data [See p.753, Col. 1, ¶2 and Fig. 1]. Goryanin teaches functions for saving or transferring models or data files [See p.750, Col. 1, ¶2 and Fig. 4A]. Goryanin teaches an optimized curve (i.e. event) when the difference between experimental and theoretical data points is calculated according to an absolute value [p.755, Col. 1, ¶ 1]. Goryanin teaches a modeling environment in communication with said analysis models and Fitter/Optimizer [Fig. 1] comprising constructing a model and a GUI for accessing the model and accepting user commands [Fig. 2]. Goryanin teaches inputting experimental data for refining the biological model [p.753, Col. 2, ¶ 2], wherein data is gathered from an “experimental platform” and/or “experimental device”. *DBsolve* is computer-readable program (i.e. article of manufacture) functionally operating on a computer system to carry out the above method steps.

Goryanin does not specifically teach gathering data from an *in situ* device on which an ongoing *in situ* experiment is conducted, as recited in claims 1, 12, 22, 28.

Goryanin does not specifically teach gathering microarray data or gathering data from a gene chip, as in claims 10, 11, and 20.

Bubendorf teaches a method of high-throughput *in situ* experimentation using tissue microarray (TMA) technology [Abstract]. Bubendorf also teaches displaying *in situ* TMA experiments [Fig. 5] and related data sets [Table 1], as in instant claims 12 and 20. Bubendorf does not specifically teach “ongoing” *in situ* experiments. However, this limitation would have been obvious to one of ordinary skill in the art since they employ a computer-assisted method. The rationale would have been to increase the number of data analyzed to improve statistical results in a clinical setting [Introduction].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to use the computer analysis program of Goryanin et al. in combination with the microarray data sets taught by Bubendorf et al, since Goryanin et al. suggest their model can analyze data from various experimental sources [Fig. 1]. One of ordinary skill in the art would have been motivated to combine the above teachings in order to accelerate tumor research using high-throughput in situ technologies [Bubendorf et al., Abstract], resulting in the practice of the instant claimed invention with predictable results.

#### ***Response to Arguments***

Applicant's arguments, filed 01/07/2009, that Goryanin and Bubendorf do not teach generating a result from a block diagram model, or gathering data directly from an in situ experimental device have been fully considered but are not persuasive. In response, Goryanin shows a block diagram describing all the system components and programs required for generating results [Fig. 1, p.753, Col. 2, ¶ 2]. Goryanin teaches gathering experimental data from an "experimental platform" and/or "experimental device" [p.753, Col. 2, ¶ 2]. Bubendorf teaches a gathering data from a high-throughput *in situ* tissue microarray [Abstract]. Therefore, the examiner maintains that the combination of references teaches and/or makes obvious the claimed limitations.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action

is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/Pablo S. Whaley/**

Patent Examiner

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/John S. Brusca/

Primary Examiner, Art Unit 1631